



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-6397]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to <https://www.reginfo.gov/public/do/PRAMain>. Find this particular information collection by selecting “Currently under Review - Open for Public Comments” or by using the search function. The OMB control number for this information collection is 0910-0782. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Food Labeling; Calorie Labeling of Articles of Food in Vending Machines and Nutrition Labeling of Standard Menu Items in Restaurants and Similar Retail Food Establishments

OMB Control Number 0910-0782--Extension

This information collection supports FDA regulations under part 101 (21 CFR part 101) and the associated collection instrument Form FDA 3757. The Federal Food, Drug, and Cosmetic Act requires the disclosure of certain calorie labeling of articles of food in vending machines, as well as nutrition information for standard menu items in certain restaurants and retail food establishments. Sections 101.8 and 101.11 (21 CFR 101.8 and 101.11) provides that respondents with a chain of 20 or more locations will disclose nutritional information of certain foods for consumers of food products for the purpose of making informed dietary choices. We also offer registration for respondents who wish to voluntarily participate with this information collection activity, for which we developed Form FDA 3757 entitled “DHHS/FDA Menu and Vending Machine Labeling Voluntary Registration” to assist respondents in this regard. To keep the registration active, a respondent renews their registration every other year within 60 days prior to the expiration of the respondent’s current registration with FDA, or it will automatically expire.

We use the collection of information to help determine compliance with regulatory requirements. Third-party disclosure requirements are used by consumers of food products for the purpose of making informed dietary choices.

Description of Respondents: Respondents to this collection of information are vending machine operators and restaurants or other similar food establishments that are subject to the requirements of part 101 as well as those entities that voluntarily participate with the provisions of this collection of information.

In the *Federal Register* of December 4, 2020 (85 FR 78334), we published a 60-day notice requesting public comment on the proposed collection of information. Although some general comments were received regarding the applicable labeling requirements, no comments suggested we revise the information collection burden we estimate under 5 CFR 1320.5(a)(1)(B).

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden¹

Activity Using Form FDA 3757; 21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Registration for Vending Machine Labeling; 101.8(d)	13	1	13	2	26
Registration Renewal for Vending Machine Labeling; 101.8(d)	19	1	19	0.5 (30 minutes)	9.5
Initial Registration for Menu Labeling; 101.11(d)	3,559	1	3,559	2	7,118
Registration Renewal for Menu Labeling; 101.11(d)	5,340	1	5,340	0.5 (30 minutes)	2,670
Total					9,823.5

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 2.--Estimated Recordkeeping Burden¹

Activity; 21 CFR Section	No. of Recordkeepers	No. of Records per Recordkeeper	Total Annual Records	Average Burden per Recordkeeping	Total Hours
Initial Burden (Annualized over 3 years)					
Initial Nutrition Analysis; 101.8(c)(2)(i)(A)	69,017	1	69,017	0.25 (15 minutes)	17,254
Annual Burden					
Recurring Nutrition Analysis; 101.8(c)(2)(i)(A)	30,059	1	30,059	0.25 (15 minutes)	7,515
Total					24,769

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Table 3.--Estimated Annual Third-Party Disclosure Burden¹

Activity; 21 CFR Section	No. of Respondents	No. of Disclosures per Respondent	Total Annual Disclosures	Average Burden per Disclosure	Total Hours
Calorie Analysis; 101.8(c)(2)(i)	282	11	3,102	1	3,102
Calorie Declaration Signage; 101.8(c)(2)(ii)	3,279	2,122	6,958,038	0.21 (12.5 minutes)	1,461,188
Vending Operator Contact Information; 101.8(e)(1)	3,279	125	409,875	0.025 (1.5 minutes)	10,247
Total					1,474,537

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: March 30, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

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